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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,196	10/02/2006	Young Chul Sung	0209.1007	3767

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EXAMINER	
BLUMEL, BENJAMIN P	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/571,196	SUNG ET AL.	
	Examiner	Art Unit	
	BENJAMIN P. BLUMEL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/08/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to comply*.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the required species in the reply filed on February 28, 2008 is acknowledged. The traversal is on the ground(s) that a search burden would not exist if the claimed antigens of viruses, bacteria, parasites and fungi were examined together. This is not found persuasive because these antigens are distinct from each other since viruses, bacteria, parasites and fungi represent distinct microbes/organisms that do not share a common characteristic, therefore creating a search burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-8 are examined on the merits.

Objections

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. The specification is objected to because pages 5 and 27 contain amino acid sequences that do not contain a specific SEQ ID NO:. Furthermore, a sequence listing is required for the claimed amino acid sequence on these pages, see Notice to Comply.

Applicants must comply with sequence rules in order to be considered a complete response to this Office Action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on March 8, 2008 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Oath/Declaration

It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76. Currently, inventor Jun Chang has changed his address based on the letter mailed on December 6, 2008, but no new Oath/Declaration has been submitted reflecting this change.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hellstrand et al. (US PGPub 2003/0039628 A1), evidenced by Hilbert et al. (Vaccine, 1999).

The claimed invention is drawn to a vaccine composition comprising an influenza virus protein/peptide and IL-12 encapsulated in a controlled release microsphere that is manufactured by double emulsion-solvent evaporation. This invention states that the

vaccine composition is for enhancing an adjuvant effect of IL-12, which the examiner is interpreting as an intended use based on MPEP § 2111.02 (II) which recites, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction."

The invention also includes a method of administering the vaccine either subcutaneously or intranasally.

Hellstrand et al. teach the administration of therapeutic compounds by controlled release from microspheres (i.e., biodegradable PLG microparticles), liposomes, gels, etc. through several routes, such as subcutaneously. Some examples of these therapeutic compounds are influenza vaccines which rely on influenza antigens. Hellstrand et al. also teach that including certain cytokines, such as IL-12, in antigenic compositions provides for a synergistic effect with regard to an increase in CTL immune responses. However, even thought Hellstrand et al. do not state that these microspheres were manufactured by double emulsion-solvent evaporation, the claimed invention is drawn to the controlled release microspheres containing certain substances and not a method of making the particles. Furthermore, the microspheres used by Hellstrand et al. would have been manufactured by such a method as evidenced by Hilbert et al. since the same method was used to produce PLG based microspheres for containing influenza antigens (see page 1066). Therefore, Hellstrand et al. anticipate the claimed invention. *See paragraphs 34, 35, 56-58, 62, 68, 83 and 91.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hilbert et al. (*supra*), Hellstrand et al. (*supra*), Chattaraj et al. (Journal of Controlled Release, 1999), Arulanandam et al. (The Journal of Immunology, 2000).

The claimed invention is drawn to a vaccine composition comprising an influenza virus protein/peptide and recombinant IL-12 encapsulated in a controlled release microsphere that is manufactured by double emulsion-solvent evaporation. This invention states that the vaccine composition is for enhancing an adjuvant effect of IL-12, which the examiner is interpreting as an intended use based on MPEP § 2111.02 (II) which recites, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction."

The invention also includes a method of administering the vaccine either subcutaneously or intranasally.

Hilbert et al. teach the development of a biodegradable PLGA microsphere that releases influenza antigens. These microspheres are manufactured by double emulsion solvent evaporation since this technique is ideal when attempting to encapsulate

hydrophilic proteins. Hilbert et al. further test these influenza antigen containing microspheres at inducing immune responses in mice following subcutaneous injection. Hilbert et al. state that using this type of encapsulated influenza antigen allows for fewer dosages to at risk subjects since the antigen is released over time, thereby increasing the duration of immune response recognition. *See pages 1065, 1066 and table 2.* However, Hilbert et al. do not teach that addition of recombinant IL-12 to the microsphere.

The teachings of Hellstrand et al. are discussed above.

Chattaraj et al. teach administering PLG and PIBCA microparticles (which release antigens) containing influenza vaccines and how different routes of administration effect immune responses in mice. Of these routes, Chattaraj et al. administered the microparticles subcutaneously. *See pages 223 and 228.* However, Chattaraj et al. do not teach the use of recombinant IL-12 in a microsphere composition.

Arulanandam et al. teach that when recombinant IL-12 is administered with influenza antigens in newborn animals, an increase in protection against lethal challenge is observed when these young animals are adults. *See pages 3698, 3701 and 3702.*

It would have been obvious to one of ordinary skill in the art to modify the compositions and methods taught by Hilbert et al. and Hellstrand et al. in order to include recombinant IL-12 with influenza antigens in controlled release microspheres, thereby enhancing the immune response to influenza antigens. One would have been motivated to do so, given the suggestion by Hilbert et al. and Hellstrand et al. that the compositions be used to induce a prolonged immune system exposure to influenza antigens in order to develop a more effective immunogenic composition. There would have been a reasonable expectation of success, given the knowledge that by co-administration of

influenza antigens and recombinant IL-12 improve the protection against lethal challenge, as taught by Arulanandam et al. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 7 recite, "…enhancing an adjuvant effect of IL-12…", however, it is unclear what the effect is relative to, thus making it an enhanced adjuvant effect. Claims 2-6 and 8 are rejected since they depend from claims 1 or 7.

Claim 4 recites, "…protein or peptide form." It is not clear what is meant by "form" and how the forms of proteins and peptides differ. The metes and bounds of the two forms cannot be determined without further definition.

Summary

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/
Primary Examiner, Art Unit 1648

/BENJAMIN P BLUMEL/
Examiner
Art Unit 1648